SEP 1 9 2000

K000727

SECTION 15

SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

1. Submitter's name, address, telephone number, contact person, and date summary prepared:

a. Company: Y-Beam Technologies, Inc.
20321 Lake Forest Drive, Suite D6
Lake Forest, CA 92630

b. Contact Person: Joseph Neev, Ph.D.
President

Joseph Neev

c. Date Summary Prepared: June 29, 2000

2. Name of device, including trade name and classification name:

a. Trade/Proprietary Name: BuffLight CLT Surgical Laser System

b. Classification Name: Surgical laser system (21 CFR 878.4810)

3. Identification of the predicate device or legally marketed device or devices to which substantial equivalence is being claimed:

The BuffLight CLT Surgical Laser is substantially equivalent to Premier Laser Systems' Aurora Diode Laser System w/ Accessories cleared under K992374. The coolant feature of this device is substantially equivalent to the OrLight 2000 Surgical Laser System by Y-Beam Technologies, Inc. cleared under K990452.

4. A description of the device that is the subject of the 510(k), including explanation of how the device functions, basic scientific concepts, significant physical and performance characteristics (design, material, physical properties):

The BuffLight CLT Surgical Laser system is a diode laser that utilizes a solid-state GaAs medium to generated light energy of 780-980nm wavelength. Laser energy is delivered to the target tissue through a handpiece.

5. Statement of intended use:

The BuffLight CLT Surgical Laser System is indicated for use in the excision, ablation, and vaporization of skin lesions, hemostasis, incision, excision, vaporization, ablation and of soft tissue, and dermabrasion.

6. Statement of how the technological characteristics of the device compare to those of the predicate or legally marketed device:

The BuffLight CLT Surgical Laser System has similar design features, functional features, and laser parameters as the predicate, legally marketed devices (Aurora diode lasers and the Y-Beam laser with coolant).

7. Brief summary of nonclinical tests and results:

The BuffLight CLT Surgical Laser System has been designed and tested to applicable safety standards. In addition, the BuffLight CLT Surgical Laser System has been carefully compared to legally marketed devices with respect to intended use and technological characteristics. The comparison presented in this 510(k) notification show that the device is substantially equivalent to predicate devices and present no new issues of safety and efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 9 2000

Y-Beam Technologies, Inc.
c/o Judy Gordon, D.V.M.
ClinReg Consulting Services, Inc.
18732 Saginaw
Irvine, California 92612

Re: K000727
Trade Name: BuffLight CLT Surgical Laser System
Regulatory Class: II
Product Code: GEX
Dated: June 29, 2000
Received: July 3, 2000

Dear Dr. Gordon:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Donna R. Vachner

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K000727

Device Name: Bufflight CLT Surgical Laser System

Indications for Use:

The BuffLight CLT Surgical Laser System is indicated for use in the excision, ablation, and vaporization of skin lesions, hemostasis, incision, excision, vaporization, ablation of soft tissue, and dermabrasion.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vochmer.

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K000727

Perscription Use X OR Over-The-Counter Use ____
(Optional Format 1-2-96)